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10/561,227	12/19/2005	Werner Mederski	MERCK-3112	6157

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
YOUNG, SHAWQUIA	

ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
05/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,227	MEDERSKI ET AL.	
	Examiner	Art Unit	
	SHAWQUIA YOUNG	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 16-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,13 and 16-21* is/are rejected.

7)☒ Claim(s) *3-12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 and 16-21 are currently pending in the instant application. Applicants have cancelled claims 14 and 15 and added new claim 21 in an amendment filed on November 30, 2007.

Information Disclosure Statement

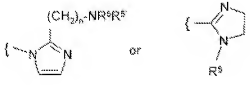
The information disclosure statement (IDS) submitted on November 30, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

I. *Response to Arguments*

Applicant's amendment, filed November 30, 2007, has overcome the rejection of claims 1-20 under 35 USC 112, first paragraph for scope of enablement; the rejection of claims 1-20 under 35 USC 112, second paragraph as being indefinite; the rejection of claims 18 and 20 under 35 USC 112, second paragraph as being incomplete for omitting essential steps; the rejection of claim 13 under 35 USC 112, second paragraph as being indefinite; the rejection of claims 9-12 under 35 USC 101 as being directed to non-statutory subject matter; the rejection of claim 20 under 35 USC 112, second paragraph as being indefinite and the objection of claims 14 and 15 as being of improper dependent form. The above rejections and objection have been withdrawn.

Applicants do not see that the instant claims 1,2, 13 and 16-20 are unpatentable over claim 1,2 and 9-16 of copending US application 10/594, 024. The Examiner wants to point out that R^3 is a monocyclic saturated, unsaturated or aromatic heterocyclic radical having from 1 to 4 N, O and/or S atoms which may be unsubstituted or mono, di

or trisubstituted by Hal, A, OA, CN, $(CH_2)_nOH$, NR^4R^5, =NH, =N-OH, =N-OA, COOA and/or carbonyl oxygen, or $CONR^4R^5$ in the instant application whereas R^4 can be



, wherein n is 0,1,2 or 3 and R^5 , $R^{5'}$ each, independently of one another denote H or A. Further all of the other variables in both the instant application and the copending application overlap. Therefore, the instant claims 1,2 13 and 16-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2 and 9-16 of copending US application 10/594,024. This rejection is maintained.

The Examiner has maintained the rejection of claims 17 and 19 under 35 USC 112, second paragraph as being indefinite for the limitation "at least one further medicament active ingredient". Applicants argue that the limitation is clearly defined in the specification (page 6). However, page 6 of the specification only discloses that the instant compounds can be used in combination with other thrombolytically active compounds and blood platelet glycoprotein receptor antagonists. Therefore applicants are only limited to the instant compounds being used in combination with the above agents. A "medicament active ingredient" is very broad and encompasses various types of agents that Applicants do not have support for.

Applicants traverse the rejection of claims 14, 15, 18 and 20 under 35 USC 112, first paragraph as failing to comply with the enablement requirement. Applicants argue that the thrust of the rejection relates to the recitation in the claims of the treatment of

cancer. Further, Applicants state that the treatment of tumor diseases is enabled by the specification (page 5, lines 4-16). Applicants state that it is well known in the art that there is a correlation between tissue factor TF/factor VIIa and the development of various types of cancer. However, the Examiner wants to point out that Applicants have not shown support that the instant compounds can treat all types of tumors, tumor diseases and/or tumor metastases (i.e. cancer). Applicants list references which teach correlation between tissue factor TF/factor VIIa and the development of various types of cancer. The Examiner wants to emphasize that the references do not teach that one class of compounds can treat all types of cancer and that is what is embraced. Simply showing that the instant compounds have a specific activity and then stating that specific references teach a correlation between the tissue factor TF/factor VIIa is not enough support for the treatment of tumors, tumor diseases and/or tumor metastasis. Applicants need to disclose actual data that shows that the instant compounds treat all types of tumors, tumor diseases and/or tumor metastasis. The Examiner wants to state that Applicants are not enabled for the treatment of migraine, tinnitus, tumors, tumor diseases and/or tumor metastasis. According to Applicants' specification, the instant compounds can be used to treat "thromboembolic diseases" such as thrombosis, myocardial infarction, arteriosclerosis, apoplexia, angina pectoris, restenosis after angioplasty and claudicatio intermittens. Therefore, Applicants are enabled for the treatment of these diseases.

The Examiner has withdrawn the rejection of claims 18 and 20 under 35 USC 112, first paragraph as failing to comply with the enablement requirement for the

treatment of thrombosis, myocardial infartion, arteriosclerosis, apoplexia, angina pectoris, restenosis after angioplasty and claudicatio intermittens. The Examiner has maintained the rejection of claims 18 and 20 under 35 USC 112, first paragraph as failing to comply with the enablement requirement for the treatment of migraine, tinnitus, tumor, tumor diseases and/or tumor metastasis.

III. *Rejection(s)*

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

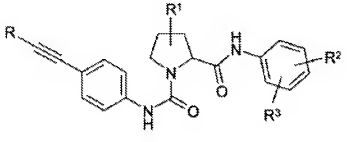
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2, 13 and 16-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 9-16 of

copending US application 10/594,024. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Applicants' elected subject matter is a compound of formula I

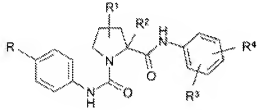


, wherein R is H, X, A, X-CO- or A-CO-; R^1 is H, =O, Hal, X, A, OH, OA, A-COO-, A-CONH-, A-CONA-, N_3, NH_2, NO_2, CN, COOH, COOA, $CONH_2$. $CON(A)_2$, O-allyl, O-propargyl, O-benzyl, =N-OH, =N-OA, $OCH_2CH(OH)CH_2OH$, A-O-CO-$(CH_2)_m$-O-, -$O(CH_2)_m$COOH or –$O(CH_2)_m$OA; R^2 is H, Hal or A; R^3 is a monocyclic saturated, unsaturated or aromatic heterocyclic radical having from 1 to 4 N, O and/or S atoms, which may be unsubstituted or mono-, di- or trisubstituted by Hal, A, OA, CN, $(CH_2)_nOH$, NR^4R^5, =NH, =N-OH, =N-OA, COOA and/or carbonyl oxygen (=O) or $CONR^4R^5$; R^2 and R^3 together are alternatively –CH=CH-NH or $–CH_2-CH_2$-NH, where one H atom may be replaced by A-CO- or A-O-CO; R^4 and R^5 independently of one another, are H or A; R^4 and R^5 together are alternatively an alkylene chain having 3, 4 or 5 carbon atoms, which may also be substituted by A, Hal, OA and/or carbonyl oxygen (=CO); X is aryl, arylalkyl, Het or Het-alkyl; A is unbranched, branched or cyclic alkyl having 1-10 carbons atoms, in which, in addition, 1-7 H atoms

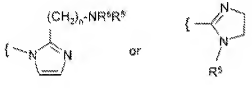
may be replaced by F and/or chlorine; Hal is F, Cl, Br or I; m is 1,2, 3, 4,5 or 6; n is 0, 1, 2, 3, 4, 5 or 6 and pharmaceutically usable derivatives, salts, solvates and stereoisomers thereof, including mixtures thereof in all ratios.

Determining the Scope and Content of the Copending Application

Claim 1 of the copending application claims a compound of the formula



, wherein R is Hal, -C≡C-H, -C≡C-A or OA ; R^1 is H, =O, Hal, A, OH, OA, A-COO-, Ph-$(CH_2)_n$-COO-, cycloalkyl-$(CH_2)_n$-COO-, A-CONH-, A-CONA-, Ph-CONA-, N_3, NH_2, NO_2, CN, COOH, COOA, $CONH_2$, CONHA, $CON(A)_2$, O-allyl, O-propargyl, O-benzyl, =N-OH, =N-OA, $=CF_2$; R^2 is H or A; R^3 denotes H, Hal or A; R^4 is C_6H_4-$(CH_2)_n$-$NR^5R^{5'}$, -$C(=NR^5)NR^5R^{5'}$,

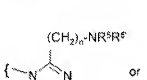


;

R^5 and $R^{5'}$ each independently of one another, denote H or A; n is 0, 1, 2, or 3 and pharmaceutically usable derivatives, salts, solvates and stereoisomers thereof, including mixtures thereof in all ratios.

Ascertaining the Differences Between the Instant Application and the Copending Application

The claims of the instant application are drawn to a broader compound genus than the claims of the copending application, which encompass the elected subject matter of the copending application. In the instant application, R^3 is a monocyclic saturated, unsaturated or aromatic heterocyclic radical having from 1 to 4 N, O and/or S atoms, which may be unsubstituted or substituted as defined in claim 1 whereas the copending application R^4 is R^4 is C_6H_4-$(CH_2)_n$-$NR^5R^{5'}$, -$C(=NR^5)NR^5R^{5'}$,



Finding Prima Facie Obviousness

As mentioned above, the genus compound of the instant application encompasses the narrower genus compound in the copending application's claims1, 2 and 9-16. The scope of the compounds in the claims 1, 2 and 9-16 of the copending application and the scope of the elected subject matter of claims 1, 2, and 13-20 of the instant application overlap and include subject matter of the copending application in the claims of the instant application. Therefore, one of ordinary skill in the art would be motivated to prepare and claim the scope of the compounds in the instant application since the scope already in the copending application is encompassed by the scope of the elected subject matter in the instant claims 1, 2, and 13-20. As a result, the claims are rejected under obviousness-type double patenting.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the treatment of thrombosis, myocardial infartion, arteriosclerosis, apoplexia, angina pectoris, restenosis after angioplasty and claudicatio intermittens, does not reasonably provide enablement for a method for the treatment of migraine, tinnitus, tumor, tumor diseases and/or tumor metastasis. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

In the instant case,

The nature of the invention

The nature of the invention is a method for the treatment of thrombosis, myocardial infarction, arteriosclerosis, inflammation, apoplexia, angina pectoris, restenosis after angioplasty and claudicatio intermittens. Support for the intended use of the instant compounds can be found in the specification at page 34 for inhibitory activity of coagulation factor Xa and coagulation factor VIIa.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.

2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of any condition considered, whether or not the condition is effected by the activity of the products of the claimed invention would make a difference.

Applicants' claims are drawn to a method for the treatment of migraine, tinnitus, tumors, tumor diseases and/or tumor metastasis.

Applicants' claims, for example, include the treatment of any tumor, tumor diseases and/or tumor metastasis (i.e. any type of cancer). The state of the prior art is that cancer therapy remains highly unpredictable. Tumors is an abnormal growth of body tissue and can be cancerous or non-cancerous. Therefore, tumors, tumor diseases and/or tumor metastasis all relate to cancer. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. Cancer is a disease characterized by a population of cells that grow and divide without respect to normal limits, invade and destroy adjacent tissues, and may spread to distant anatomic sites through a process called metastasis (URL:http://en.wikipedia.org/wiki/ Cancer>). Most cancers are named for where they start. For example, lung cancer starts in the lung, and breast cancer starts in the breast. Symptoms and treatment depend on the cancer type and how advanced it is ((<URL:http://www.nlm.nih.gov/medlineplus/print/> cancer.html>). It is known that the challenge of cancer treatment has been to target specific therapies to

pathogenetically distinct tumor types, that cancer classification has been based primarily on morphological appearance of the tumor and that tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub et al. page 531). Treatment may include surgery, radiation, chemotherapy, immunotherapy, monoclonal antibody therapy, etc. Furthermore, it is known that chemotherapy is most effective against tumors with rapidly dividing cells and that cells of solid tumors divide relatively slowly and chemotherapy is often less effective against them. It is also known in the prior art (Lala et al. page 91) that the role of NO in tumor biology remains incompletely understood with both the promotion and inhibition of NO mentioned for the treatment of tumor progression and only certain human cancers may be treated by selected NO-blocking drugs. These example shows that there are different cellular mechanisms, the unpredictability in the art and the different treatment protocols. Because "cancer" refers to a class of diseases, it is unlikely that there will ever be a single "cure or treatment for cancer".

Applicants' claims are also drawn to a method for the treatment of tinnitus. Tinnitus is also known as ringing in the ears when there is no outside source of the sounds. Tinnitus is common but it is not known exactly what causes a person to hear sounds with no outside source of the noise. However, tinnitus can be a symptom of almost any ear problem, including ear infections, foreign objects or wax in the ear and injury from loud noises. Alcohol, caffeine, antibiotics, aspirin, or other drugs can also cause ear noises. Tinnitus may occur with hearing loss. Occasionally, it is a sign of high blood pressure, an allergy or anemia. Rarely, tinnitus is a sign of a serious problem like

a tumor or aneurysm. If a doctor can determine the cause, fixing the problem (for example, removing ear wax) may make the symptoms go away. Many medicines have been used to relieve symptoms of tinnitus but no drug works for everyone. ((<URL:http://www.nlm.nih.gov/medlineplus/ency/article/003043.htm>)

Applicants' claims are also drawn to a method for the treatment of migraines. A migraine is a recurring, throbbing headache that usually occurs on one side of the head. Migraine is a biological disorder that affects about 28 million Americans. There are various types of migraine triggers, which may include: diet (missed meals, alcohol, foods that contain MSG), sleep, stress, environmental factors, hormonal changes, etc. Many women have attacks linked to their menstrual cycles. Menstrual migraines can be more severe than other migraines and more difficult to treat. Typically, acute treatments are used to stop an attack when it occurs or to treat its symptoms. Pain relieving drugs include, aspirin, ibuprofen, acetaminophen or prescription nonsteroidal anti-inflammatory drugs and analgesics. Specific drugs used to stop migraine attacks include: Triptans (i.e. sumatriptan, zolmitriptan, etc.) and Ergot alkaloids (i.e. dihyroergotamine).

((<URL:http://www.thebrainmatters.org/index.cfm?key=1.9.6>)

The amount of direction present and the presence or absence of working examples

The only direction or guidance present in the instant specification is minimal. The specification only gives a list of conditions considered to be treated by the

compounds of formula I. There are no working examples present for the treatment of any specific disease or disorder.

Test assays and procedure are provided in the specification at page 34 for inhibitory activity of coagulation factor Xa and coagulation factor VIIa. It is inconceivable as to how the claimed compounds can treat the extremely difficult diseases embraced by the instant claims.

Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The breadth of the claims

The breadth of the claims is a method for the treatment of thrombosis, myocardial infarction, arteriosclerosis, inflammation, apoplexia, angina pectoris, restenosis after angioplasty, claudicatio intermittens, migraine, tinnitus, tumors, tumor diseases and/or tumor metastasis.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what diseases selected from migraine, tinnitus, tumors, tumor diseases and/or tumor metastasis would be benefited by the activity of the

claimed compounds of formula I and would furthermore then have to determine which of the claimed compounds in the instant invention would provide treatment of the diseases.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* or *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

The specification fails to provide sufficient support of the broad use of the claimed compounds of the invention for the treatment of migraine, tinnitus, tumors, tumor diseases and/or tumor metastasis. As a result necessitating one of skill to perform an exhaustive search for which diseases can be treated by what compounds of the invention in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the

compound encompassed in the instant claims, with no assurance of success.

This rejection can be overcome, for example, by deleting the diseases migraine, tinnitus, tumors, tumor diseases and /or tumor metastasis.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 17-19 recites the limitation "at least one further medicament active ingredient". On page 6 of the specification, it is stated that the compound can be employed with other thrombolytically active compounds or blood platelet glycoprotein receptor (IIb/IIIa) antagonists, but the specification does not state if these compounds are what is considered "one further medicament active ingredient" and fails to defined the term or teach exactly what is meant by "one further medicament active ingredient". Thus, "at least one further medicament active ingredient" is not defined so as to know the metes and bounds of the claims. Therefore, the claims are indefinite.

Dependent Claim Objections

Dependent Claims 3-12 are also objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.

IV. Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626